

## CARDIOVASCULAR SYSTEMS INC. (CSI)

### DIAMONDBACK 360® CORONARY ORBITAL ATHERECTOMY SYSTEM

#### SALIENT CHARACTERISTICS

**Indications:** The DIAMONDBACK 360® Coronary Orbital Atherectomy Systems (OAS) are percutaneous orbital atherectomy systems indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to *de novo*, severely calcified coronary artery lesions.

**Contraindications:** The OAS are contraindicated when the VIPERWIRE guide wire cannot pass across the coronary lesion or the target lesion is within a bypass graft or stent. The OAS are contraindicated when the patient is not an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy, or has angiographic evidence of thrombus, or has only one open vessel, or has angiographic evidence of significant dissection at the treatment site and for women who are pregnant or children.

**Warnings/Precautions:** Performing treatment in excessively tortuous vessels or bifurcations may result in vessel damage; The OAS were only evaluated in severely calcified lesions, A temporary pacing lead may be necessary when treating lesions in the right coronary and circumflex arteries; On-site surgical back-up should be included as a clinical consideration; Use in patients with an ejection fraction (EF) of less than 25% has not been evaluated.

See the instructions for use before performing DIAMONDBACK 360 coronary orbital atherectomy procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events.

Diamondback 360 Coronary OAS Micro Crown 1.25mm , 6Fr

- **Product Information**

- First and only device specifically indicated for severe calcium
- Easy setup and use
- Control of device in operating field
- .012" OAS guide wire
- Compatible with 6 French guiding catheters